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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,471	10/23/2001	Eriko Takano	0380-P02329US1	5210
110	7590	10/03/2003		EXAMINER
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,471	TAKANO ET AL.	
	Examiner Kathleen M Kerr	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 March 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Claims 1-32 as originally filed are pending in the instant application.

Claim Numbering

2. Prior to restriction, the claim numbering was corrected. No claim 20 was filed, and duplicate claim 26's were filed. Moreover, some dependencies had to be interpreted.

- a) The claim following Claim 19 is now **Claim 20** (depending from Claim 19).
- b) Claim 22 is now **Claim 21** (depending from Claim 20).
- c) Claim 23 is now **Claim 22** (depending from Claim 21).
- d) Claim 24 is now **Claim 23** (depending from Claim 22).
- e) Claim 25 is now **Claim 24**. (analogous to Claim 15)
- f) Claim 26 is now **Claim 25** (depending from Claim 24). (analogous to Claim 16)
- g) Claim 26 (second occurrence) has remained **Claim 26**, but depending from Claim 25. (analogous to Claim 17)
- h) Claim 27 has remained **Claim 27**, but depending from Claim 26. (analogous to Claim 18)
- i) Claim 28 has remained **Claim 28**, but depending from Claim 24. (analogous to Claim 19)

Amendment may be required prior to a first Office action on the merits if these are, indeed, the dependencies intended for examination.

Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1, 9, 11, 13, 15, and 19-23, drawn to methods of modifying or identifying *Streptomyces* host cells to increase antibiotic production by deleting the scbA gene and drawn to the cells made, classified in class 435, subclass 471.

- II. Claims 2-4 and 16-18, drawn to methods of making antibiotics using a *Streptomyces* host cell with a deleted scbA gene, classified in class 435, subclass 76.
- III. Claims 5, 10, 12, 14, 24, and 28-32, drawn to methods of modifying or identifying *Streptomyces* host cells to increase antibiotic production by deleting the scbR gene and drawn to the cells made, classified in class 435, subclass 471.
- IV. Claims 6-8 and 25-27, drawn to methods of making antibiotics using a *Streptomyces* host cell with a deleted scbR gene, classified in class 435, subclass 76.

4. The inventions are distinct, each from the other because of the following reasons:

The products in Group I and the methods of Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the products can be used for a materially different process of using the product, such as the identification of scbA homologs in a screening assay (since the *Streptomyces* cell is scbA⁻). Thus, Groups I and II are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups I and III are related by virtue of making products with deleted, related genes, either scbA or scbR. While the Groups are related, they are distinct because scbA and scbR are distinct structural and functional genes giving the products made wholly distinct structures. Also, because scbA and scbR are distinct, the individual method steps are distinct. Thus, Groups I and III are patentably distinct. Because these inventions are distinct for the reasons given above and the search required for Group I (scbA) is not required for Group III (scbR), particularly in textual and sequence databases, restriction for examination purposes as indicated is proper.

The methods of Groups I and IV are related by virtue of making or using products with deleted, related genes, either scbA or scbR. While the Groups are related, they are distinct because scbA and scbR are distinct structural and functional genes giving the products made wholly distinct structures. Also, because scbA and scbR are distinct and because different products are made (a host cell strain or an antibiotic), the individual method steps are distinct. Thus, Groups I and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups II and III are related by virtue of making or using products with deleted, related genes, either scbA or scbR. While the Groups are related, they are distinct because scbA and scbR are distinct structural and functional genes giving the products made wholly distinct structures. Also, because scbA and scbR are distinct and because different products are made (a host cell strain or an antibiotic), the individual method steps are distinct. Thus, Groups II and III are patentably distinct. Because these inventions are distinct for the

reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups II and IV are related by virtue of making products with deleted, related genes, either scbA or scbR. While the Groups are related, they are distinct because scbA and scbR are distinct structural and functional genes giving the products made wholly distinct structures. Also, because scbA and scbR are distinct, the individual method steps are distinct. Thus, Groups II and IV are patentably distinct. Because these inventions are distinct for the reasons given above and the search required for Group II (scbA) is not required for Group IV (scbR), particularly in textual and sequence databases, restriction for examination purposes as indicated is proper.

The products in Group III and the methods of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the products can be used for a materially different process of using the product, such as the identification of scbR homologs in a screening assay (since the *Streptomyces* cell is scbR). Thus, Groups III and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

5. The Examiner notes that if product claims in Groups I or III are found directed to an allowable product, then processes of using said products in Group II or IV, respectively, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re Ochiai*, and *In re Brouwer*). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

6. A telephone call was made to Patrick Hagan on September 26, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

7. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK 
September 26, 2003